DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: FOSAMAX®
Docket No. 96E-0036

#24



MAY 17 1996

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,621,077, filed by Instituto Gentili S.p.A., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for FOSAMAX®, the human drug product claimed by the patent.

The total length of the regulatory review period for FOSAMAX® is 2,558 days. Of this time, 2,375 days occurred during the testing phase and 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 29, 1988.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on September 29, 1988.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: March 31, 1995.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for FOSAMAX® (NDA 20-560) was initially submitted on March 31, 1995.

3. The date the application was approved: September 29, 1995.

   FDA has verified the applicant's claim that NDA 20-560 was approved on September 29, 1995.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Melvin Winokur
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